49. (New) The apparatus as set forth in claim 28, wherein the control unit receives the measurement value from the measurement unit and adjusts the control parameter at least partly on the basis of the measurement value; and wherein the control parameter comprises a property of the fluidizing gas flow, and the control unit adjusts the control parameter by controlling the flow unit.

50. (New) The apparatus as set forth in claim 33, wherein the property of the fluidizing gas flow is flow rate, moisture content, or temperature.

51. (New) The apparatus as set forth in claim 49, wherein the property of the fluidizing gas flow is flow rate, moisture content, or temperature.

52. (New) The apparatus as set forth in claim 34, wherein the property of the droplet is size, generation rate, or concentration of a constituent.

53. (New) The apparatus as set forth in claim 41, wherein the pharmaceutical product is a pellet, tablet, or capsule.

REMARKS

Claims 1-20 and 24-41 have been amended to more clearly define the invention and to place the claims in accordance with U.S. patent practice. The exemplary embodiments recited in claims 10-12, 20, 33, 34, and 41 have been deleted and embodied in new claims 43-46, 48, and 50-53. The dependencies of claims 3-7, 9-20, 26, 28-31, and 33-41 have been amended to remove the occurrence of an improper multiple claim dependency. In this regard, claims 10 and 12-14 have been amended to incorporate the embodiment of claim 7, and claims 33-36 have been amended to incorporate the embodiment of claim 32. Claim 27 has been amended to substitute the term "chamber" for the term --housing--. Support for the amendment is found on page 7, lines 15-24, of the specification.

Claims 22 and 23 have been amended to recite a method for controlling the coating process of a batch of particles which are monitored in accordance with the claimed invention. Support for the amendments to claims 22 and 23 is found on page 5, lines 5-35. Claim 21 has been canceled.

New claim 42 is directed to an embodiment of the invention deleted from claim 10 and comprises a combination of claims 7 and 10. New claim 47 is directed to an embodiment of the invention deleted from amended claim 13. New claim 49 is directed to an embodiment of the invention deleted from claim 33 and comprises a combination of claims 33 and 32.

No new matter has been inserted by any amendments herein.

Upon entry of this Preliminary Amendment, claims 1-20 and 22-53 are pending. Applicants respectfully submit that claims 1-20 and 22-53 are directed to patentable subject matter. Accordingly, Applicants request allowance of the claims.

Authorization is hereby given to charge any fee due in connection with this communication to Deposit Account No. 23-1703.

Dated: June 24, 2002

Respectfully submitted,

Andrew Fessak

Andrew Fessak
Reg. No. 48,528
Agent for Applicants
Customer No. 07470
Direct Line: (212) 819-8437

Claims 1-20 and 22-41- Version with markings t show changes made

1. A method for [of] monitoring the formation of a coating on a single particle [(P)], comprising the steps of:

(a) arranging the particle [(P)] at a given spatial location;

(b) forming the [said] coating on the particle [(P)]; and

(c) performing a spectroscopic measurement on the coating while the coating is being formed on the particle to obtain [obtaining] a measurement value of at least one principal parameter related to the [said] coating [, characterized in that said measurement value is obtained by performing a spectrometric measurement on said coating during said step of forming said coating].

2. [A] The method as set forth in claim 1, wherein the [said] spectrometric measurement is performed continuously during at least part of the coating formation step to generate [of forming the said coating, thereby generating] a sequence of measurement values of the [said at least one] principal parameter.

3. [A] The method as set forth in claim 1 [or 2], wherein the [said] step of arranging the particle [(P)] at the [a] given spatial location comprises [includes] fluidizing the [said] particle [(P)] on an upwardly directed gas flow.

4. [A] The method as set forth in claim 3 [any one of claims 1-3], wherein the coating formation [said step of forming said coating on the particle (P)] comprises [includes] generating a single droplet [(D)] of a coating fluid, and bringing the [said] droplet to impinge [on] upon the [said] particle [(P)].

5. [A] The method as set forth in claim 4 [claims 3 and 4], wherein the [said] droplet [(D)] upon [said] generation is moved into and allowed to follow the [said] upwardly directed gas flow to the [said] particle [(P)].

6. [A] The method as set forth in claim 4 [or 5], wherein the step of generating a [said] single droplet [(D)] is repeated [repeatedly generated], thereby forming at least one stream of [such] droplets [(D) that] which sequentially impinge upon the [on said] particle [(P)].

7. [A] The method as set forth in claim 1 [any one of the preceding claims], further comprising the [a] steps of:
monitoring at least one control parameter related to the particle or its environment [of the particle (P) or the particle (P) itself,]; and
[a step of] identifying a functional relationship between the [said at least one] control parameter and the [said at least one] principal parameter.

8. [A] The method as set forth in claim 7, further comprising the [a] step of generating [, based on said functional relationship for said single particle (P),] an aggregate model for prediction of the influence of the [said at least one] control parameter on the [said at least one] principal parameter for a large number of [such] particles [(P)] based on the functional relationship for the single particle.

9. [A] The method as set forth in claim 7 [or 8], further comprising the step of adjusting the [changing said at least one] control parameter [based,] at least partly [,] on the basis of the [said] measurement value.

10. [A] The method as set forth in [any one of claims 7-9 in combination with] claim 3 [or 5], further comprising the steps of:
a) monitoring at least one control parameter related to the particle or its environment; and
b) identifying a functional relationship between the control parameter and the principal parameter,

wherein the [said at least one] control parameter comprises [includes] a property of the [said] gas flow [, such as a flow rate, a temperature or a content of a solvent].

11. [A] The method as set forth in claim 7 [any one of claims 7-9], wherein the [said at least one] control parameter comprises [includes] a property of the particle [(P), such as a size, a shape, a density or a porosity].

12. [A] The method as set forth in claim 4 [any one of claims 7-9 in combination with any one of claims 4-6], further comprising the steps of:
monitoring at least one control parameter related to the particle or its environment; and
identifying a functional relationship between the control parameter and the principal parameter,

wherein the [said at least one] control parameter comprises [includes] a property of the [said] droplet [(D), such as a droplet size, a droplet generation rate or a concentration of a droplet constituent].

13. [A] The method as set forth in claim 4 [any one of claims 7-9 in combination with any one of claims 4-6], further comprising the steps of:
monitoring at least one control parameter related to the particle or its environment; and
identifying a functional relationship between the control parameter and the principal parameter,

wherein the [said at least one] control parameter comprises [includes a] the duration of a wetting period during the coating formation step [said step of forming said coating, said wetting period being effected by controlling said droplet generation].

14. [A] The method as set forth in claim 4 [any one of claims 7-9 in combination with any one of claims 4-6], further comprising the steps of:
monitoring at least one control parameter related to the particle or its environment; and
identifying a functional relationship between the control parameter and the principal parameter,

wherein the [said at least one] control parameter comprises the [includes a] duration of a drying period during the coating formation step [said step of forming said coating].

15. [A] The method as set forth in claim 1 [any one of the preceding claims], wherein the [said] step of obtaining the [said] measurement value comprises:

c1) [includes] generating a sample vector of measurement data from the [said] spectrometric measurement; [,] and

c2) condensing the [said] measurement data into the [said] measurement value of the [said at least one] principal parameter.

16. [A] The method as set forth in any one of claims 1-15 and 42-47 [the preceding claims], wherein [said] the spectrometric measurement is performed by means of near-infrared spectrometry.

17. [A] The method as set forth in any one of claims 1-15 and 42-47 [the preceding claims], wherein the [said] spectrometric measurement is performed by means of a spectrometric method based on Raman scattering.

18. [A] The method as set forth in any one of claims 1-15 and 42-47 [the preceding claims], wherein the [said] spectrometric measurement is performed by means of a spectrometric method based on absorption in the UV, visible, or infrared (IR) wavelength region, or luminescence or [, such as] fluorescence emission.

19. [A] The method as set forth in any one of claims 1-15 and 42-47 [the preceding claims], wherein the [said] spectrometric measurement is performed by means of imaging spectrometry.

20. [A] The method as set forth in any one of claims 1-15 and 42-47 [the preceding claims], wherein the [said] particle [(P)] is a pharmaceutical product [, such as a pellet a tablet or a capsule].

22. (Amended) [Use of a method as set forth in claim 2] A method for controlling the [of a] coating process of a batch of particles, comprising the steps of:

a) monitoring the coating formation according to claim 2;

b) using the [wherein said] sequence of measurement values of the principal parameter [is used] as a sequence of reference values in the [said] control; [,] and [wherein]
c) obtaining a corresponding spectroscopic measurement [is effected] on the [said] batch of particles to provide a sequence of actual values for the [said] control.

23. (Amended) [Use of a method as set forth in any one of claims 1-20] A method for controlling the [of a] coating process of a batch of particles, comprising the steps of: [, wherein]
a) monitoring the coating formation according any one of claims 1-15 and 42-47;
b) identifying a functional relationship [is identified] between [said] at least one principal parameter and at least one simultaneously-monitored control parameter, wherein the control parameter [which] is related to an environment of a [said] single particle of the batch; [(P); wherein]
c) selecting one or more [of said at least one] control parameters, based on the [said] functional relationship, [is selected] to represent one or more of the [said at least one] principal parameters;
d) determining [wherein] a desired sequence of values of the [said one or more] selected control parameter(s) [parameters is determined] for the [said] single particle [(P)]; and [wherein said]
e) controlling the coating process of the [a] batch of particles [is controlled] based on the [said] desired sequence of selected control parameter values.

24. An apparatus for monitoring the formation of a coating on a single particle [(P),] comprising:
means [(2, 5, 6, 9)] for arranging the [said] particle [(P)] at a given spatial location; [, and]
a fluid supply unit for applying [(3) adapted to apply] a coating fluid to the [said] particle to form a coating; and [(P) such that said coating is formed, characterized by]
a measurement unit [(4)] which [is adapted to] performs a spectrometric measurement on the [said] coating during formation thereof, and [to] derives a measurement value of at least one principal parameter related to the [said] coating.

25. [An] The apparatus as set forth in claim 24, wherein the [said] measurement unit [(4) is adapted to] continuously performs the [said] spectrometric measurement [,] and ther by

generates [generating] a sequence of measurement values of the [said at least one] principal parameter.

26. [An] The apparatus as set forth in claim 24 [or 25], wherein the [said] particle arranging means [(2, 5, 6, 9)] comprises a flow unit [(2)] which [is adapted to] generates a fluidizing gas flow upon [on] which the particle [(P)] is fluidized.

27. [An] The apparatus as set forth in claim 26, further comprising a chamber [housing (1)] in which the [said] coating is formed on the [said] particle [(P)], wherein the [said] flow unit [(2) is adapted to] provides a shielding gas inside the chamber [housing (1)] intermediate the measurement unit [(4)] and the location of the [said] particle, and wherein the [(P), said] shielding gas is substantially [being essentially] identical to the gas used for fluidizing the [said] particle [(P)].

28. [An] The apparatus as set forth in claim 24 [any one of claims 24-27], wherein the [said] fluid supply unit [(3) is operable to] generates a single droplet of the coating fluid which [(D) that] is brought to impinge upon the [on said] particle [(P)].

29. [An] The apparatus as set forth in claim [26 and] 28, wherein the [said] fluid supply unit [(3) is arranged to] injects each droplet of the coating fluid [(D)] into the [said] fluidizing gas flow.

30. [An] The apparatus as set forth in claim 28 [or 29], wherein the [said] fluid supply unit [(3) is arranged to] repeatedly generates [said] single droplets of the coating fluid and [(D),] thereby forms [forming] a stream of such droplets which [(D) that] sequentially impinge upon the [on said] particle [(P)].

31. [An] The apparatus as set forth in claim 24 [any one of claims 24-30], further comprising a control unit [(5)] which monitors [is adapted to monitor] at least one control parameter related to the particle or its environment [of the particle (P) or the particle (P) itself].

32. [An] The apparatus as set forth in claim 31, wherein the control unit [(5) is adapted to] receives the [said] measurement value from the [said] measurement unit and adjusts the [(4) and to effect a change of said at least one] control parameter [based,] at least partly [,] on the basis of the [said] measurement value.

33. [An] The apparatus as set forth in [claim 32 in combination with] claim 26 [or 28], wherein the control unit receives the measurement value from the measurement unit and adjusts the control parameter at least partly on the basis of the measurement value; and wherein the [wherein said at least one] control parameter comprises [includes] a property of the [said] fluidizing gas flow, [such as a flow rate, a moisture content or a temperature,] and [wherein] the [said] control unit [(5) is operable to effect said change] adjusts the control parameter by controlling the [said] flow unit [(2)].

34. [An] The apparatus as set forth in claim 28 [32 in combination with any one of claims 28-30], wherein the control unit receives the measurement value from the measurement unit and adjusts the control parameter at least partly on the basis of the measurement value; and wherein [wherein said at least one] the control parameter comprises [includes] a property of the droplet [said droplets, such as a droplet size, a droplet generation rate or a concentration of a droplet constituent], and the [wherein said] control unit [(5) is operable to effect said change] adjusts the control parameter by controlling the [said] fluid supply unit [(3)].

35. [An] The apparatus as set forth in claim 28 [32 in combination with any one of claims 28-30], wherein the control unit receives the measurement value from the measurement unit and adjusts the control parameter at least partly on the basis of the measurement value; and wherein the [said at least one] control parameter comprises the [includes a] duration of a droplet generation period; [,] and the [wherein said] control unit [(5) is operable to effect said change] adjusts the control parameter by controlling the [said] fluid supply unit [(3)].

36. [An] The apparatus as set forth in claim 28 [32 in combination with any one of claims 28-30], wherein the control unit receives the measurement value from the measurement unit and adjusts the control parameter at least partly on the basis of the measurement value; and wherein the [said at least one] control parameter comprises the [includes a] duration of a drying period, and the [wherein said] control unit [is operable to effect said change] adjusts the control parameter by controlling the [said] fluid supply unit [(3)].

37. [An] The apparatus as set forth in any one of claims 24-36 and 49-52, wherein the [said] measurement unit [(4) is adapted to] performs the [said] spectrometric measurement by means of near-infrared spectrometry.

38. [An] The apparatus as set forth in any one of claims 24-36 and 49-52 [24-37], wherein the [said] measurement unit [(4) is adapted to] performs the [said] spectrometric measurement by means of a spectrometric method based on Raman scattering.

39. [An] The apparatus as set forth in any one of claims 24-36 and 49-52 [24-38], wherein the [said] measurement unit [(4) is adapted to] performs the [said] spectrometric measurement by means of a spectrometric method based on absorption in the UV, visible, or infrared (IR) wavelength region, or luminescence or [, such as] fluorescence emission.

40. [An] The apparatus as set forth in any one of claims 24-36 and 49-52 [24-39], wherein the [said] measurement unit [(4) is adapted to] performs the [said] spectrometric measurement by means of imaging spectrometry.

41. [An] The apparatus as set forth in any one of claims 24-36 and 49-52 [24-40], wherein the [said] particle [(P)] is a pharmaceutical product [, such as a pellet, a tablet or a capsule].